

### **Remarks/Arguments**

Reconsideration of this application, as amended, is respectfully requested.

#### **I. Status of the Claims**

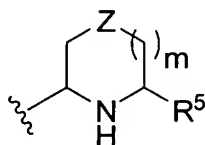
Claims 1, 6-9, 11-15 and 17 are pending. Claims 2-5 and 10 are canceled to comply with the restriction requirement. Claims 1, 6 and 11 are amended to comply with the restriction requirement. Claim 15 is amended to correct a clerical error.

No new matter is added by these amendments.

#### **II. Restriction Requirement and Lack of Unity of Invention**

The Examiner states that claims 1-15 and 17 are subject to a lack of unity of invention under PCT Rule 13.2. The Examiner requires election of one six claim groups.

As noted by the Examiner, in a telephone conference dated January 20, 2006, the undersigned elected prosecution of the Group VI claims, without traverse. Group VI covers claims 1-13 (in part), covering compounds and compositions wherein  $X^1$  is H,  $X^2$  is OH, and  $R^1$  is



The Examiner states that as a result of the election, the remaining subject matter of claims 1-13, 15 and 17 which is not within Group VI is withdrawn from prosecution.

In response, the claims are amended to limit prosecution to the Group VI claims.

In view of the action taken, it is requested that the restriction requirement be withdrawn.

#### **III. Rejections Under 35 U.S.C. § 112, First Paragraph**

Compound claims 1-13 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds of lack of written description. The Examiner states as follows:

The specification discloses general information of the said compounds on the activity in inhibiting the  $\beta$ -secretase enzyme with IC<sub>50</sub> from 1 nM to 1  $\mu$ M. However, it fails to specify which claimed compounds possess what kind of  $\beta$ -secretase inhibiting activity. The  $\beta$ -secretase inhibiting activity of the claimed compounds cannot be validated accurately.

Applicants traverse the rejection, on the grounds that the claims meet the written description requirement of section 112. The touchstone for satisfaction of the written description requirement is whether the application contains "sufficient information in the specification to show that the inventor

possessed the invention at the time of that original disclosure.” *Pandrol USA LP v. Airboss Railway Prods Inc.*, 76 USPQ2d 1524, 1526 (Fed. Cir. 2005). Here, the rejected claims are part of the original disclosure, and contain literal support in the specification.

Further, the Examiner has not presented an explanation as to why there is a lack of written description, other than the statement that the specification “fails to specify which compounds possess what kind of  $\beta$ -secretase inhibiting activity.” There is no requirement in the law for applications claiming a genus of compounds having a stated utility, that the specification provide data of the disclosed utility for each of the exemplified compounds. Here, pending claims 1, 6-9 and 11-15 claims a series of phenylcarboxamide compounds, and claim 17 claims the use of the claimed compounds for treating Alzheimer’s Disease. The compounds are unambiguously identified by a structural formula, and the specification contains a description of the synthesis of the compounds. In addition, the specification identifies several exemplified compounds in the examples section of the specification, by structure, synthesis and experimental data. The specification also discloses a biological utility for the compounds (inhibition of the beta secretase enzyme, see page 15, lines 1-7) and a pharmaceutical utility (treatment of Alzheimer’s Disease, see page 15, lines 12-20). At page 20, lines 14-17, the specification states that compounds of the invention have beta secretase inhibition activity with an  $IC_{50}$  of from about 1 nM to 1  $\mu$ M. Hence, it is not seen how the claims lack written description, or more precisely, how the specification demonstrates a lack of possession of the invention by the inventors.<sup>1</sup>

Notwithstanding the arguments above, applicants submit the enclosed Declaration of Ming-Tain Lai (unexecuted). An executed version of Dr. Lai’s declaration will follow.

Dr. Lai’s declaration presents experimental data of BACE1 inhibition of six of the compounds exemplified in pending claim 11. As the declaration shows, the exemplified compounds all demonstrate an  $IC_{50}$  inhibition of less than 1  $\mu$ M, which is within the range stated in the specification. The declaration expressly rebuts the stated reasoning for the written description rejection.

In view of the action taken and arguments made, it is believed that the above-referenced rejection under 35 U.S.C. § 112, first paragraph, has been overcome. It is respectfully requested that the rejection be withdrawn.

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<sup>1</sup> The Examiner’s rejection is also at odds with the PTO’s “Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1, Written Description Requirement,” 66 Federal Register 1099 (Jan. 5, 2001). The PTO Guidelines state that possession of the invention (in the context of the written description requirement), “may be shown by a clear description of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention.” *Id.* at 1105. In the section entitled “Methodology for Determining Adequacy of Written Description, the guidelines set forth a process for examination of written description. The process repeatedly advises that the written description requirement can be met by description by chemical structure. *See id.* at 1105-1107.

**IV. Claim Objections**

Claims 14 and 15 are objected to. The Examiner states that claim 14 is objected to as dependent upon a rejected base claim, but would be allowable if rewritten in independent form. The objection has been overcome in view of the amendments to the claims, limiting the claims to the elected subject matter.

Claim 15 is objected to because of a clerical error. In view of the amendment to claim 15, it is requested that the objection be withdrawn.

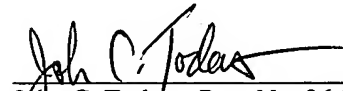
**V. Conclusion**

In view of the action taken and arguments made, it is believed that all pending claims 1, 6-9, 11-15 and 17 are now in condition for allowance.

Favorable action is earnestly solicited.

Respectfully submitted,

By

  
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